K030629

SEP - 4 2003

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Dolphin Medical 2150 Handheld Pulse Oximeter

Submitting by

Dolphin Medical Inc.
12525 Chadron Avenue
Hawthorne, CA 90250

Submission Correspondent

Bill Curnan
Regulatory Specialist
9433 S. Morning Glory Lane
Highlands Ranch, CO 80130

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Common, Classification & Proprietary Names

Common Name:	oximeter
Classification Name:	oximeter
Proprietary Name:	Dolphin Medical 2150 Handheld Pulse Oximeter

Predicate Devices

The Dolphin Medical 2150 Handheld Pulse Oximeter is substantially equivalent to the following devices:

K024235	Dolphin Stand Alone Pulse Oximeter and Accessories
K020075	Dolphin Stand-Alone Pulse Oximeter and Accessories
K953817	Aristo Medical Model 2101 Patient Monitor

Device Description

The Dolphin Medical 2150 Pulse Oximeter consists of the Dolphin ONE™ OEM 701 Module technology, and works with existing Dolphin ONE extension cables, and oximetry sensors to non-invasively calculate the functional saturation of arterial hemoglobin (SpO2) and pulse rate. It also includes a thermistor port which accepts off the shelf approved YSI 400 series patient temperature sensors for the reading of patient temperature. It features an easy-to-read display that presents patient data and status information: an LCD (liquid crystal display) display that shows the SpO2, pulse rate values, patient temperature, and other messages as appropriate.

A Dolphin ONE Extension Cable connects the sensor to the 2150. The cable is available in two configurations, three foot or eight in length.

The oximeter can be operated off either an internal rechargeable battery or with use of a medical grade AC power supply which is furnished with the unit.

The Dolphin Medical Model 2150 Pulse Oximeter will be used for continuous noninvasive monitoring and spot checking of SpO2, pulse rate, and patient temperature for adult, pediatric. infant and neonatal patients in hospitals and hospital-type facilities. Typical acute-care uses are the Operating Room, Recovery Room and the Adult and Neonatal Intensive Care Units. The Dolphin Medical Model 2150 Pulse Oximeter and accessories will be used for adult, pediatric and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The user responsible for the operation of the Dolphin Medical Model 2150 will normally be a licensed clinical professional such as a physician, nurse, or respiratory therapist.

Intended Use

The Dolphin Medical 2150 Handheld Pulse Oximeter is indicated for use for spot checking and/or continuous noninvasive monitoring of fractional oxygen saturation of arterial hemoglobin, pulse rate, and patient temperature. The 2150 is for use with adult pediatric and neonatal patients in hospitals and hospital type facilities.

Technological Characteristics Comparison

The Dolphin 2150Handheld Pulse is a redesign of the Dolphin 2100 Stand Alone Pulse Oximeter (K002036) into a handheld configuration with the addition of a temperature sensor port.

The Dolphin Model 2150 Pulse Oximeter incorporates the Dolphin OEM 701 Oximeter Engine in a handheld Oximeter with patient temperature monitoring capability and an infra red printer interface.

Dolphin Medicals OEM 701 Module is a complete pulse oximeter engine, based on a patented Digital Signal Processing technology with a high speed 128 MHz RISC processor. This circuit board interfaces directly with the Dolphin ONE™ family of sensors and the host platform to calculate the SpO2 and pulse rate. It provides the required sensor drive currents, accepts the sensor data, runs the algorithms to calculate SPO2, Pulse Rate, and patient temperature and provides a digital output to the host unit for display. Additionally, the board contains all necessary support for direct connection to off the shelf YSI 400 series thermistor patient temperature probes.

The OEM 701 is a redesign of the OEM 601 which is the oximetry engine for the Dolphin Model 2100(k002036).

The Dolphin ONE Sensors measure light absorption of blood from two light emitting diodes. Oxygen saturated blood absorbs light differently as compared to unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood.

Performance Testing

- **Biocompatibility**

  Biocompatibility tests, appropriate for skin-contacting devices for prolonged exposure, have been performed on all Dolphin ONE sensors

- **Electrical Safety**

  The Dolphin Medical 2150 Handheld Pulse Oximeter was designed to comply with the following standards:

  1. CSA C22.2 No. 601.1
  2. EN 60601-1, and Amendments 1 and 2
  3. EN 60601-1-2, 2002
  4. EN 475 1995
  5. EN 865: 1997
  6. FDA Guidance Document for Pulse Oximeters: 9/7/1992
  7. ASTM 1415:1992,
  8. UL2601-1: Second Edition, 1997
  9. IEC 6068-2-6
  10. IEC 6068-2-27
  11. IEC 6068-2-64
  12. ISTA Procedure 2A
  13. E1112-00

Clinical Testing

The 2150 was validated using Dolphin ONE Sensors in breathe-down protocols at the VA Hospital of Wisconsin – Milwaukee, (Dr. Phillip Clifford, MD.). Scientific accuracy was demonstrated by statistically comparing Dolphin 2150 SpO_2 values to functional SaO2 values. Volunteers participated in the breathe-down protocol while fully conscious at SaO2 values ranging from 70-100%. Data was analyzed to determine the ARMS for each probe. Clinical Validation for the Dolphin ONE Reusable, Adult disposable, Neonatal disposable resulted in an accuracy determination of less then 2.0% A_{RMS} in the range of 70-100% Sa02 for adults, pediatrics, and infants and less than 3.5% Arms in the range of 70-100 for Neonates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2003

Mr. Bill Curnan
Regulatory Specialist
Dolphin Medical Incorporated
9433 S. Morning Glory Lane
Highlands Ranch, Colorado 80130

Re: K030629
Trade/Device Name: Dolphin ONE 2150 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 17, 2003
Received: June 18, 2003

Dear Mr. Curnan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

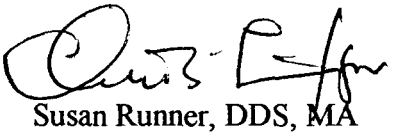
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. STATEMENT OF INDICATIONS FOR USE (FDA FORM)

510(k): K030629

Device: **Dolphin ONE 2150 Pulse Oximeter**

Indications for Use:

The Dolphin Medical 2150 Handheld Pulse Oximeter is indicated for use for spot checking and/or continuous noninvasive monitoring of fractional oxygen saturation of arterial hemoglobin, pulse rate, and patient temperature. The 2150 is for use with adult pediatric and neonatal patients in hospitals and hospital type facilities.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030629

prescription device ✓